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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,970	02/11/2004	Koji Kishi	3190-011-01	3712

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KILYK & BOWERSOX, P.L.L.C.
53 A EAST LEE STREET
WARRENTON, VA 20186

EXAMINER	
GITOMER, RALPH J	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,970	KISHI ET AL.	
	Examiner	Art Unit	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

The IDS and Preliminary amendment received 2/11/04 have been entered and claims 14-35 are currently pending in this application. Please update the specification regarding the status of the related cases.

The present claims appear to be directed to a kit for determining HDL where the kit contains hydrazine in combination with a surfactant. The function of the hydrazine is stated to be ion strength increasing.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 34-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The method claims are directed to two method steps, providing and utilizing. The use of something is not statutory subject matter.

The claims may be directed to a kit for determining HDL with two reagents, the first containing cholesterol esterase, NAD+, hydrazine, a surfactant, the second containing cholesterol dehydrogenase, a surfactant.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-22, 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokusai.

Kokusai (JP 5-176797) entitled "Determination of Cholesterol for Clinical Examination Over Wide pH Range", English translation provided, teaches in the abstract, determining cholesterol with a first reagent containing cholesterol esterase, NAD+, Triton X-100, and 50 mM hydrazine, and a second reagent containing cholesterol dehydrogenase, and Triton X-100.

The claims differ from Kokusai in that they are directed to a kit, and claim the source from which the enzymes are derived from.

It would have been obvious to one of ordinary skill at the time the invention was made to employ the reagents of Kokusai in a kit for the well known advantages of providing a kit including commercial success, convenience, economic efficiency. Regarding the source of the enzymes in the kit, all the claimed enzymes are commercially available and no novelty is seen in either the enzymes or their sources.

Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kokusai as applied to claims 14-22, 26-33 above, and further in view of Applicants admissions in the specification.

The claims differ from the abstract of Kokusai in that they include a third enzyme that reacts with the LDL, although not specifically reacts only with LDL.

The present specification teaches on page 13, the free cholesterol in the LDL, VLDL and chylomicron may be preliminarily reacted with COD or CDH to convert into cholestenone hydrazone in the presence of hydrazine to make a non-substrate state for the time of assaying HDL. The technology for converting the free cholesterol into a non-substrate is well known and taught in Kokusai.

It would have been obvious to one of ordinary skill at the time the invention was made to employ a third enzyme to remove interfering substances with the teachings of Kokusai because the reagents taught by Kokusai would inherently react with different forms of cholesterol in a selective fashion. To first remove interferents prior to performing an assay is well known and taught in some of the references cited herein.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Note that 37 CFR 1.115 states that for applications filed after 9/21/04, preliminary amendments filed at the time of the original filing are not new matter. However, this application was filed 2/11/04.

The claims are either directed to a kit or a method of employing a kit but the specification as originally filed does not disclose any kit. There also may be issues regarding the proper priority date of this application where the documents from which priority is claimed also do not disclose a kit.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The claims are directed to a kit but lack any kit or apparatus limitations. The claims state there are two reagents but it is unclear if they are combined or separate. The preamble of claim 14 is unclear as to what may be intended, detecting cholesterol or HDL. It is noted the claims are directed only to detecting. In claim 14 "ion strength increasing compound" is unclear as no ions are seen nor how one would increase their strength as ions have no strength. In claim 14 "reacting cholesterol" does not state with what it is reacted. In claim 17 "or more" reads on infinity which would not work in the invention. Claim 21 contains many instances of lack of antecedent basis such as "the oxide".

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kozak (5,460,974) teaches assaying HDL.

Nakamura (6,333,166) teaches determining LDL.

Kishi (6,114,134) teaches determining HDL.

Kishi (JP 11-155595) teaches determining cholesterol.

Shirahase (JP 11-18798) teaches determining cholesterol.

Sato (JP 2000-325097) published 11/2000, teaches determining HDL.

Ismail (5,185,247) teaches hydrazine in cholesterol tests for stabilizing enzymes.

Fuji (JP 9-285298) entitled "Test Reagent for Determination of HDL Cholesterol in Lipid Fraction of Serum or Plasma", English translation provided, teaches in the abstract, a test reagent including cholesterol esterase, cholesterol oxidase, cholesterol dehydrogenase, polyanion, divalent metal salt, nonionic surfactant.

Nakamura (6,057,118) entitled "Method for Quantitatively Determining LDL Cholesterols" teaches in column 3 last paragraph bridging to column 4, known enzymatic methods of determining cholesterol employ a combination of cholesterol esterase and cholesterol oxidase and cholesterol esterase and cholesterol dehydrogenase. In column 4 lines 19-21, an additional reaction accelerating agent is added to accelerate reaction of LDL. These agents are surfactants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ralph Gitomer
Primary Examiner
Art Unit 1655

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200